Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed January 21, 2009. Currently, claims 1-48 and 51-61 remain pending. Claims 1-48 and 51-61 have been rejected. In this amendment, claims 56 and 57 have been amended. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 112

On page 2 of the Office Action, claims 60 and 61 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description. In particular, the Office Action asserted that the disclosure does not describe "one or more electroactive polymers, wherein the one or more electroactive polymers are configured to expand when activated by an electric current" of claim 60. Applicant must respectfully disagree. Applicant must respectfully assert that numerous portions of the specification as filed provide support for "one or more electroactive polymers, wherein the one or more electroactive polymers are configured to expand when activated by an electric current". For example, paragraphs 14, 47, 49, 50 and 58 of the published application recite:

> [0014] The collars are at least partially constructed of an electro-active polymer (EAP) which expands to a predetermined extent upon exposure to an electric current. In some embodiments the collars are exposed to the electric current by a conductive element. A second conductive element is provided by exposing the fluid that inflates the balloon, which is typically saline and/or a radiopaque solution) to a similar electrical current. In some embodiments the EAP material of the collar and/or the collar itself will expand about 0.5% to about 20% expansion in a predetermined manner and/or direction when subjected to an electric current of 0.001 microAmps to 1 milliAmps (-2 to +2 V). In at least one embodiment a collar is constructed of one or more conductive elements such as gold, silver, platinum, etc., which is at least partially surrounded by a layer of EAP material.
>
> [0047] In order to allow the balloon 16 to rotate freely relative to the shaft or shafts 12 and 14 each waist 20 and 22 of the balloon 16 is engaged to a collar 30 and 32 respectively. Collars 30 and 32 are at least partially constructed of EAP material such including of Poly-pyrrole (PPY), Poly-Aniline (PAni), Poly-Thiofene (PTH), Poly-Paraphenylene Vinylene (PPV), Nafion, Bucky paper or any other ionic electro-active polymer that is considered to have low voltage, low speed, high stress (up to 500 MPa), characteristics. EAP materials have the unique characteristic of expanding in size when exposed to an electric current of predetermined current or voltage. For example, in some embodiments the EAP material of the collar and/or the collar itself will expand about 0.5% to about 20%

> when exposed to an electric current of 0.001 microAmps to 1 milliAmps (-2 to +2 V).
>
> [0049] As a result of EAP materials unique expansion characteristics a collar comprising EAP material such as collars 30 and 32 may be formed to have a pre-current shape and a post-current shape that is different or larger than the pre-current shape.
>
> [0050] Pre-current refers to the condition of the collars 30 and 32 before the collars are exposed to an electric current sufficient to activate the EAP material. Post-current refers to the condition of the collars 30 and 32 when the collars are being exposed to an electric current sufficient to activate the expansion of the EAP material.
>
> [0058] As indicated above the collars 30 and 32 are at least partially constructed of **one or more EAP materials**. However, in order to more effectively transmit the electric current to the EAP material in some embodiments, such as shown in FIGS. 2-5, the collars 30 and 32 include a conductive member or marker 34 about which at least one layer 36 of EAP material is engaged. The markers 34 may be any type of conductive material or materials and is preferably biocompatible. Appropriate materials for the construction of the markers 34 include but are not limited to, gold, platinum, nitinol, silver, etc. The layer 36 of EAP material may partially or entirely surround the marker 34.

As can be seen in the foregoing passages, the present application clearly provides sufficient support for the limitation "one or more electroactive polymers, wherein the one or more electroactive polymers are configured to expand when activated by an electric current" of claim 60. As such, withdrawal of the rejection is respectfully requested.

Allowable Subject Matter

Nowhere in the Office Action did the Examiner reject claims 60 and 61 over prior art references. As such, and because claims 60 and 61 are believed to be in compliance with § 112, first paragraph, claims 60 and 61 are believed to be allowable. Accordingly, Applicant respectfully requests such indication in the next Office Action. Alternatively, if the Examiner disagrees, Applicant respectfully requests a new Non-Final Office Action detailing the grounds of rejection.

Claim Rejections – 35 USC § 102

On page 2 of the Office Action, claims 1, 28-30, 32-33, 35-40, 56, and 58-59 were rejected under 35 U.S.C. 102(e) as being anticipated by Gumm (U.S. Publication No. 2003/0055483). After careful review, Applicant must respectfully traverse this rejection.

Turning to claim 1, which recites:

> 1. (Previously Presented) A catheter assembly comprising:
> a catheter shaft, the catheter shaft having a length and an outer surface;
> a balloon, the balloon comprising a proximal balloon waist, a distal balloon waist and a body portion therebetween, the balloon having an expanded state and a unexpanded state, in the expanded state the body portion having an expanded diameter and in the unexpanded state the body portion having an unexpanded diameter that is less than the expanded diameter; and
> a proximal collar and a distal collar, the proximal collar fixed to the catheter shaft and the distal collar fixed to the catheter shaft, each collar having a nonactivated state and an activated state, in the nonactivated state the distal balloon waist being rotatable about the distal collar and the proximal balloon waist being rotatable about the proximal collar, in the activated state the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage the distal balloon waist.

Nowhere does Gumm appear to teach or suggest "a proximal collar and a distal collar, the proximal collar fixed to the catheter shaft and the distal collar fixed to the catheter shaft, each collar having a nonactivated state and an activated state, in the nonactivated state the distal balloon waist being rotatable about the distal collar and the proximal balloon waist being rotatable about the proximal collar, in the activated state the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage the distal balloon waist", as recited in claim 1.

Instead, Gumm appears to teach a catheter assembly having a rotatably mounted balloon that can be advanced to a vessel bifurcation along first and second guidewires. (See abstract). The catheter assembly appears to include a tubular member or hypotube 14 having a distal fixed body 20 and a proximal fixed body 22 non-rotatably secured to the distal end and proximal end of the hypotube 14. (See paragraph 39). Further, paragraph 40 of Gumm recites:

> [0040] A first rotating member or distal rotating member 24 and a second rotating member or proximal rotating member 26 are axially spaced apart and located between the distal fixed body 20 and proximal fixed body 22. The rotating members 24 and 26 are preferably of the same general diameter throughout their length and rotate freely about the axis of the main hypotube 14.

(Emphasis added). As can be seen, the rotating members 24 and 26 rotate freely about the axis of the main hypotube 14. Further, "[a] distal end 30 of the catheter balloon is sealingly joined to (or integrally formed with) the distal rotating member 24 while a proximal end 32 of the catheter balloon is sealingly joined to (or integrally formed with) the proximal rotating member 26. Thus, the balloon is free to rotate relative to the main hypotube" (paragraph 41). (Emphasis added). From this, it is clear that Gumm teaches the proximal and distal rotating members are joined to or integrally formed with the balloon to allow the balloon to freely rotate about the main hypotube. Contrary to claim 1, the proximal and distal rotating members are not fixed to the catheter shaft. As such, nowhere does Gumm appear to teach or suggest "a proximal collar and a distal collar, the proximal collar fixed to the catheter shaft and the distal collar fixed to the catheter shaft, each collar having a nonactivated state and an activated state, in the nonactivated state the distal balloon waist being rotatable about the distal collar and the proximal balloon waist being rotatable about the proximal collar", as recited in claim 1.

On page 8 of the Office Action, the Examiner asserts that, as seen in Figure 1 of Gumm, when viewed from a bird's eye point of view, it is possible for the proximal collar 24 to be fixed to the catheter 14 and the distal collar 20 to be fixed to the catheter shaft, while citing paragraph 40. However, paragraph 40 recites:

> [0040] A first rotating member or distal rotating member 24 and a second rotating member or proximal rotating member 26 are axially spaced apart and located between the distal fixed body 20 and proximal fixed body 22. The rotating members 24 and 26 are preferably of the same general diameter throughout their length and rotate freely about the axis of the main hypotube 14.

Further paragraph 41 recites:

> [0041] Sealed to the proximal and distal rotating members 24 and 26 are opposite ends of a catheter balloon 28. A distal end 30 of the catheter balloon is sealingly joined to (or integrally formed with) the distal rotating member 24 while a proximal end 32 of the catheter balloon is sealingly joined to (or integrally formed with) the proximal rotating member 26. Thus, the balloon is free to rotate relative to the main hypotube, a feature that provides advantages and benefits over known stent assemblies. It is also contemplated that the rotating members 24 and 26 can be formed of sealing or elastomeric material (or incorporate a separate seal member) so that slight axial movement of the balloon 28 and of the rotating members 24 and 26 engages and seals against the fixed bodies 20 and 22 upon inflation of the balloon 28. The balloon 28 and the rotating members 24 and 26 can hold high pressure and seal at the ends. It will be appreciated that the rotating members 24 and 26 are preferably constructed to maintain a cylindrical

> configuration under pressure so that the balloon 28 is free to rotate relative to the main hypotube 14 when pressurized.

(Emphasis added). Clearly, the rotating members 24 and 26 rotate freely about the axis of the main hypotube 14 and move axially to engage and seal against fixed bodies 20 and 22 upon inflation of the balloon regardless of the point of view. Therefore, nowhere does Gumm appear to teach or suggest "a proximal collar and a distal collar, the proximal collar fixed to the catheter shaft and the distal collar fixed to the catheter shaft, each collar having a nonactivated state and an activated state, in the nonactivated state the distal balloon waist being rotatable about the distal collar and the proximal balloon waist being rotatable about the proximal collar", as recited in claim 1.

Furthermore, nowhere does Gumm appear to teach or suggest "each collar having a nonactivated state and an activated state ... in the activated state the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage the distal balloon waist". Instead, Gumm appears to teach or suggest pressurizing the balloon to cause axial movement of the rotating members to seal the balloon. Nothing appears to teach the proximal collar or the distal collar being expanded.

In the Office Action, the Examiner cites paragraph 41 and 45 as teaching or suggesting "the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage the distal balloon waist". The cited passages recite:

> [0041] Sealed to the proximal and distal rotating members 24 and 26 are opposite ends of a catheter balloon 28. A distal end 30 of the catheter balloon is sealingly joined to (or integrally formed with) the distal rotating member 24 while a proximal end 32 of the catheter balloon is sealingly joined to (or integrally formed with) the proximal rotating member 26. Thus, the balloon is free to rotate relative to the main hypotube, a feature that provides advantages and benefits over known stent assemblies. It is also contemplated that the rotating members 24 and 26 can be formed of sealing or elastomeric material (or incorporate a separate seal member) so that slight axial movement of the balloon 28 and of the rotating members 24 and 26 engages and seals against the fixed bodies 20 and 22 upon inflation of the balloon 28. The balloon 28 and the rotating members 24 and 26 can hold high pressure and seal at the ends. It will be appreciated that the rotating members 24 and 26 are preferably constructed to maintain a cylindrical configuration under pressure so that the balloon 28 is free to rotate relative to the main hypotube 14 when pressurized.

> [0045] An enlarged view of the side branch hypotube opening 64 in the stent 50 is shown in FIG. 5. The side branch hypotube 60 exits from underneath the proximal end of the stent. Upon deployment of the stent 50, the side branch hypotube opening 64 allows for unobstructed blood flow to the ostium of the side branch passage. As will also be appreciated, the side branch hypotube 60 is fixed or secured to the exterior of the balloon. Thus, the side branch hypotube 60, balloon 28, and rotating members freely rotate as a unit relative to the main hypotube 14 for accurate, passive positioning with the side guide wire and thus accurate positioning of the stent 50 relative to a saddle point of the bifurcated passage. With continued reference to FIG. 2, the catheter balloon 28 is inflated, the stent 50 is deployed, and the rotating members 24 and 26 are interlocked with the fixed members 20 and 22 to stop the rotating action of the stent delivery system and create a pressure tight system.

Nowhere do these passages appear to teach or suggest the rotating members 24 and 26 being expandable. Additionally, no other portion of Gumm appears to teach or suggest "each collar having a nonactivated state and an activated state ... in the activated state the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage the distal balloon waist", as recited in claim 1.

As the Examiner is well aware, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (MPEP § 2131). As discussed previously, Gumm appears to fail to teach each and every element of claim 1. Therefore, for at least these reasons, claim 1 is believed to be not anticipated by Gumm and withdrawal of the rejection is respectfully requested. For similar reasons and others, claims 28-30, 32-33, and 35-40, which depend from claim 1 and include additional limitations, are believed to be not anticipated by Gumm and withdrawal of the rejection is respectfully requested.

Turning to claim 56, which recites:

> 56. (Currently Amended) A catheter assembly comprising:
> a catheter shaft, the catheter shaft having a length and an outer surface;
> a balloon disposed about at least a portion of the outer surface of the catheter shaft, the balloon comprising a proximal balloon waist, a distal balloon waist and a body portion there between, the balloon having an expanded state and a unexpanded state, in the expanded state the body portion having an expanded diameter and in the unexpanded state the body portion having an unexpanded diameter that is less than the expanded diameter; and

> one or more collars disposed between the outer surface of the catheter shaft and at least one of the proximal waist and distal waist of the balloon, the one or more collars including an electroactive polymer material having a contracted state and an expanded state, wherein the balloon is rotatable relative to the catheter shaft when the electroactive polymer material of the one or more collars [[are]] is in the contracted state and the balloon is sealingly engaged to the catheter shaft when the electroactive polymer material of the one or more collars [[are]] is in the expanded state.

Nowhere does Gumm appear to teach or suggest "one or more collars disposed between the outer surface of the catheter shaft and at least one of the proximal waist and distal waist of the balloon, the one or more collars including an electroactive polymer material having a contracted state and an expanded state, wherein the balloon is rotatable relative to the catheter shaft when the electroactive polymer material of the one or more collars is in the contracted state and the balloon is sealingly engaged to the catheter shaft when the electroactive polymer material of the one or more collars is in the expanded state", as recited in claim 56. Further, nowhere has the Examiner cited any portion of Gumm as teaching or suggesting such limitations. In fact, the Examiner failed to address claim 56 anywhere in the Office Action besides merely stating claim 56 in the statement of rejection. Therefore, for at least these reasons, claim 56 is believed to be patentable over Gumm and withdrawal of the rejection is respectfully requested.

For similar reasons and others, claims 58 and 59, which depend from claim 56 and include additional limitations, are believed to be not anticipated by Gumm and withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 USC § 103

On page 4 of the Office Action, claims 2, 5, 16-21, 31, 47-48, and 57 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (U.S. Publication No. 2003/0055483) in view of Gerberding et al. (U.S. Patent No. 6,315,790). After careful review, Applicant must respectfully traverse this rejection. For similar reasons discussed above, independent claims 1 and 56 are believed to be patentable over Gumm and nothing in Gerberding et al. appears to remedy the noted shortcomings. Therefore, for similar reasons and others, some of which are discussed below, claims 2, 5, 16-21, 31, 47-48, and 57, which depend from one of claims 1 and 56, are believed to be patentable over Gumm in view of Gerberding et al.

Turning to claim 2, which recites:

> 2. (Original) The catheter assembly of claim 1 wherein the collars are actuated between the nonactivated state and the activated state by exposure to an electric current.

As can be seen, claim 2 recites "the collars are actuated between the nonactivated state and the activated state by exposure to an electric current". Nothing in Gumm or Gerberding et al. appear to teach or suggest such a limitation.

In the Office Action, the Examiner merely states that Gerberding teaches marker bands (30) that are at least partially radiopaque and detectable by X-ray. Nowhere does this statement appear to even address the limitation of claim 2 that recites "the collars are actuated between the nonactivated state and the activated state by exposure to an electric current". For at least these reasons, claim 2 is believed to be patentable over Gumm and Gerberding et al. Applicant respectfully requests that if the Examiner is to maintain this rejection, the Examiner point out with particularity where the cited references teach the limitations of claim 2.

On page 5 of the Office Action, the Examiner refers to claims 2-5, 20-21, 47-48 and 57 and points to element 44 of Figure 6 of U.S. Patent No. 6,432,064 and element 38 of Figure 3 of U.S. Patent No. 5,425,703. However, as indicated above, the statement of the rejection states claims 2, 5, 16-21, 31, 47-48, and 57 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (U.S. Publication No. 2003/0055483) in view of Gerberding et al. (U.S. Patent No. 6,315,790). As such, it is unclear to the Applicant what the rejection is. In particular, it is unclear which claims the Examiner is rejecting, such as claims 3-5. Further, it is unclear what references the Examiner is relying on. Are U.S. Patent No. 6,432,064 and U.S. Patent No. 5,425,703 being relied on? Applicant reminds the Examiner that "[w]here a claim is refused for any reason relating to the merits thereof it should be "rejected" and the ground of rejection fully and clearly stated, and the word "reject" must be used." (MPEP § 707.07). As such, Applicant respectfully asserts that all claims being rejected and all references relied on should be positively included in the statement of rejection so that the rejections are clear. Accordingly, Applicant respectfully requests clarification of the rejection in a new Non-Final Office Action so that Applicant may be afforded an opportunity to respond.

Also on page 5 of the Office Action, the Examiner refers to claims 6-11, 13-14, 19, 22-27, 31, and 46 and cites to U.S. Patent No. 4,838,859; U.S. Patent No. 4,906,244; U.S. Patent No. 4,950,239; U.S. Patent No. 5,290,306; and U.S. Publication No. 2002/0146557. However,

as mentioned previously, the statement of the rejection states claims 2, 5, 16-21, 31, 47-48, and 57 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (U.S. Publication No. 2003/0055483) in view of Gerberding et al. (U.S. Patent No. 6,315,790). As such, it is unclear to Applicant what the rejection is. In particular, it is unclear whether claims 6-11, 13-14, 22-27, and 46 are being rejected and whether the Examiner is relying on U.S. Patent No. 4,838,859; U.S. Patent No. 4,906,244; U.S. Patent No. 4,950,239; U.S. Patent No. 5,290,306; and U.S. Publication No. 2002/0146557 in making the rejection. Applicant reminds the Examiner that "[w]here a claim is refused for any reason relating to the merits thereof it should be "rejected" and the ground of rejection fully and clearly stated, and the word "reject" must be used." (MPEP § 707.07). As such, Applicant respectfully asserts that all claims being rejected and all references relied on should be positively included in the statement of rejection so that the rejections are clear. Accordingly, Applicant respectfully requests clarification of the rejection in a new Non-Final Office Action so that Applicant may be afforded an opportunity to respond.

While it is unclear whether the Examiner is rejecting claim 22 and, if so, what references the Examiner is relying, nothing in Gumm or Gerberding appear to teach or suggest "wherein the proximal collar and the distal collar are comprised of electro-active polymer (EAP) material", as recited in claim 22. For at least these reasons, claim 22 is believed to be patentable over the cited references.

In any event, as discussed previously, independent claims 1 and 56 are believed to be patentable over Gumm and nothing in the other cited references appear to remedy the noted shortcomings. Therefore, claims 2-55 and 57-59, which depend from one of claims 1 and 56, are believed to be patentable over the cited references.

On page 5 of the Office Action, claim 34 was rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (U.S. Publication No. 2003/0055483) in view of Marton (U.S. Publication No. 2001/0032013). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 1 is believed to be patentable over Gumm and nothing in Marton appears to remedy the above-noted shortcomings. Therefore, claim 34, which depends from claim 1 and includes additional limitations, is believed to be clearly patentable over Gumm in view of Marton.

On page 6 of the Office Action, claims 41, 42, and 46 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (U.S. Publication No. 2003/0055483) in view of

Pinchuk et al. (U.S. Publication No. 2001/0107330). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 1 is believed to be patentable over Gumm and nothing in Pinchuk et al. appears to remedy the above-noted shortcomings. Therefore, claims 41, 42, and 46, which depend from claim 1 and include additional limitations, are believed to be clearly patentable over Gumm in view of Pinchuk et al.

Also, on page 6 of the Office Action, the Examiner refers to claims 51-55 and states that "Gumm in view of Pinchuk discloses the invention substantially as claimed". However, nowhere in the Final Office Action does the Examiner expressly rejected claims 51-55. Applicant reminds the Examiner that "[w]here a claim is refused for any reason relating to the merits thereof it should be "rejected" and the ground of rejection fully and clearly stated, and the word "reject" must be used." (MPEP § 707.07). Applicant respectfully requests clarification of the rejection in a new Non-Final Office Action so that Applicant may be afforded an opportunity to respond. However, for similar reasons discussed previously, and others, claim 1 is believed to be patentable over Gumm and nothing in Pinchuk et al. appears to remedy the above-noted shortcomings. Therefore, claims 51-55, which depend from claim 1 and include additional limitations, are believed to be clearly patentable over Gumm in view of Pinchuk et al.

On page 7 of the Office Action, claims 43-45 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (U.S. Publication No. 2003/0055483) in view of Pinchuk et al. (U.S. Patent No. 2002/0107330). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 1 is believed to be patentable over Gumm and nothing in Pinchuk et al. appears to remedy the above-noted shortcomings. Therefore, claims 43-45, which depend from claim 1 and include additional limitations, are believed to be clearly patentable over Gumm in view of Pinchuk et al.

Conclusion

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: 4-21-2009

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